

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle Carton label

1. Name of the medicinal product

[HA485 trade name]* Lamivudine/zidovudine 150 mg/300 mg tablets
Lamivudine/zidovudine

2. Statement of active substance

Each film-coated tablet contains 150 mg lamivudine, 300 mg zidovudine.

3. List of excipients

4. Pharmaceutical form and contents

30 film-coated tablets

60 film-coated tablets

90 film-coated tablets

5. Method and route of administration

Oral use

Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP MM/YYYY

9. Special storage conditions

Store at or below 30°C and protect from light. The bottle should be kept tightly closed.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

No special requirements

11. Name and address of the supplier

Micro Labs Ltd
#31, Race Course Road
560001 Bangalore
Karnataka

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

India

Tel: + 91 80 2237 0451 to 2237 0457

Fax: + 91 80 2237 0463

E-mail: jainethesh@microlabs.in

12. WHO Reference Number (Prequalification Programme)

HA485

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA485 trade name][†] Lamivudine/zidovudine 150 mg/300 mg tablets
Lamivudine/zidovudine

2. Statement of active substance

Each film-coated tablet contains 150 mg lamivudine, 300 mg zidovudine.

3. List of excipients

4. Pharmaceutical form and contents

30 film-coated tablets

60 film-coated tablets

90 film-coated tablets

5. Method and route of administration

Oral use

Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP MM/YYYY

9. Special storage conditions

Store at or below 30°C and protect from light. The bottle should be kept tightly closed.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

No special requirements

11. Name and address of the supplier

Micro Labs Ltd
#31, Race Course Road
560001 Bangalore
Karnataka

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India
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12. WHO Reference Number (Prequalification Programme)

HA485

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton label

1. Name of the medicinal product

[HA485 trade name][‡] Lamivudine/zidovudine 150 mg/300 mg tablets

Lamivudine/zidovudine

2. Statement of active substance

Each film-coated tablet contains 150 mg lamivudine, 300 mg zidovudine.

3. List of excipients

4. Pharmaceutical form and contents

10 x 10 film-coated tablets

5. Method and route of administration

Oral use

Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP MM/YYYY

9. Special storage conditions

Store at or below 30°C and protect from light. The bottle should be kept tightly closed.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

No special requirements

11. Name and address of the supplier

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#31, Race Course Road
560001 Bangalore
Karnataka
India
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e-mail: jainethesh@microlabs.in

12. WHO Reference Number (Prequalification Programme)

HA485

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

PVDC/PVC-Aluminium foil blister

1. Name of the medicinal product

[HA485 trade name] Lamivudine/zidovudine 150 mg/300 mg tablets

Lamivudine/zidovudine

2. Name of the supplier

Micro Labs Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other